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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,142	02/27/2004	Clement Wan Chye Meng	P-5169D11	9263

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EXAMINER

RAMANA, ANURADHA

ART UNIT PAPER NUMBER

3732

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/789,142	Applicant(s) MENG ET AL.	
	Examiner Anu Ramana	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/21/2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

Revised Figure 3, submitted on December 21, 2004, is not in compliance with 37 CFR 1.121(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6-10 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Genese et al. (US 4,496,348).

Genese et al. disclose a catheter assembly 10 including a catheter 12, a catheter hub 14 attached to a proximal end of catheter 12, a needle 18 having a needle hub 20 attached to the proximal end 22 of needle 18 and an elastic sealing member or "elastomeric septum" 30 within a slide with a retaining member or "housing" having a

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particular or "fixed" or "finite" length (42, 44A, 46A and 49) (Fig. 4E, col. 7, lines 4-25 and lines 62-68 and col. 8, lines 1-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5 and 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo et al. (US 6,551,283) in view of Genese et al. (US 4,496,348).

Guo et al. disclose a cannula or "catheter" assembly 70 with an introducer sheath or "catheter" 100 attached to a hub or "adapter" 90, a valve gasket or "septum" 20 with a centering hole or "cavity" 24, a cap or "septum housing" 80 wherein the housing extends over a portion of the proximal face of the septum and has a particular or "fixed" or "finite" length and an elongated cylindrical medical device 120 disposed in the sheath 100 (Figures 1 and 10, col. 5, lines 32-67, col. 6, lines 1-64, col. 9, lines 11-67 and col. 10, lines 1-15).

Guo et al. disclose all elements of the claimed invention except that the elongated cylindrical medical device is a needle.

Genese et al. teach that it is known in the art to provide an elongated cylindrical medical device such as a needle with a needle hub in a catheter hub for insertion of a catheter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a needle with a needle hub in the Guo et al. assembly, as taught by Genese et al., for the purpose of catheter insertion.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of Meng et al. (U.S. 6,506,181) in view of Genese et al. (US 4,496,348).

Patented claim 12 discloses all elements of the claimed invention except for a proximal end of the septum holder or "housing" extending over at least a portion of the proximal face of the septum.

Genese et al. teach a septum housing with a retaining member 49 covering the proximal face of a sealing member or "septum" 30 to hold the sealing member inside a catheter hub by an interference or friction fit (Fig. 4E, col. 7, lines 4-25 and lines 62-68 and col. 8, lines 1-10).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a housing in the invention of claim 12 such that a portion of the housing covers a proximal face of the septum, as taught by Genese et al., to retain the septum inside the hub.

Regarding claims 5, 6, 11, 12 and 18, the Applicants do not disclose the criticality of the extent or "length" of the septum housing. It would have been an obvious matter of design choice to change the length of the septum housing, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claims 10-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of Meng et al. (U.S. 6,719,726) in view of Genese et al. (US 4,496,348).

Patented claim 11 discloses all elements of the claimed invention except for an adapter and a proximal end of the septum holder or "housing" extending over at least a portion of the proximal face of the septum.

Genese et al. teach a septum housing with a retaining member 49 covering the proximal face of a sealing member or "septum" 30 to hold the sealing member inside a catheter hub or "adapter" by an interference or friction fit (Fig. 4E, col. 7, lines 4-25 and lines 62-68 and col. 8, lines 1-10).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a housing in the invention of patented claim 11 such that a portion of the housing covers a proximal face of the septum, as taught by Genese et al., to retain the septum inside the hub.

Regarding claim 11, the Applicants do not disclose the criticality of the extent or "length" of the septum housing. It would have been an obvious matter of design choice to change the length of the septum housing, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on December 21, 2004 have been fully considered but are not persuasive for the following references.

In response to applicants' arguments that the references fail to show certain features of applicants' invention, it is noted that the feature (i.e., "septum housing having a variable length," see page 7, lines 1-2 of "REMARKS") is not recited in the rejected

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claims. The amended claims recite the limitation, "particular length" so the Examiner is assuming that the Applicants' meant "particular length."

Genese et al. disclose septum housing (42, 44A, 46A and 49) to have a "particular" or "fixed" or "finite" length (Figure 4E). Genese et al. further disclose that the housing compresses sealing member or "septum" 30 (col. 7, lines 62-68 and col. 8, lines 1-10).

Guo et al. also disclose that cap or "housing" 80 has a "particular" or "fixed" or "finite" length and applies a compressive force on valve gasket or "septum" 20 (Figures 1, 10 and col. 6, lines 33-40).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Amrutha Ramana*
March 3, 2005

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